Council for Responsible Nutrition

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0276, Registration of Facilities, Implementation of Bioterrorism Act of 2002

The Council for Responsible Nutrition (CRN) is one of the leading trade associations in the dietary supplement industry. CRN represents a broad spectrum of companies ranging from ingredient suppliers to finished product manufacturers, including both brand name products and private label products. Our member companies market their products in all distribution channels, including the mass market, natural food stores, multilevel marketing, and mail order. Our supplier members include companies that make or market all classes of ingredients incorporated into dietary supplements, including vitamins and minerals, amino acids, botanical ingredients, specialty products, and excipients.

CRN's member companies are committed to fully evaluating their procedures with regard to helping ensure that their facilities and products are secure from potential bioterrorism threats, and we are anxious to work with FDA in this important area.

Our members will be impacted by the new requirement for registration of facilities in the same manner as other firms in the conventional food industry, and some of the concerns we share with the general food industry are outlined below. Special attention is called to our deep concern over the expansion of the registration (and prior notice) regulations to cover packaging. **In addition, we have a unique concern relating to the treatment of independent distributors in direct selling companies.**

Independent Distributors in Direct Selling Companies Should Be Defined as "Retailers" for purposes of the registration requirement.

CRN's members include several prominent direct sales firms, including Nutrilite, Shaklee, Herbalife, GNLD, Mary Kay and the Unicity network. These companies market their products through independent distributors or "individual business owners" -- individuals who purchase products at wholesale from the parent company, for sale to consumers. These independent distributors function as "retailers" to the consumer. We do not have a good estimate of the total number of such individual independent

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distributors, but we are reliably informed that each of the major direct selling firms may have a few hundred thousand independent distributors. Although "distributor" is the term used to describe these individuals, in industry parlance, they are not "distributors" as the term is generally used within the conventional food industry.

In addition, within each company's network of independent distributors, a fraction of the distributors qualify as supervisors. These individuals sell products to their own network of distributors, who in turn sell the products to consumers. In some companies, 15 to 20 percent of the individual distributors may fall into the category of supervisors who both sell direct to consumers and also sell product wholesale to their own network of independent distributors, who in turn sell direct to consumers. In each direct selling company, the number of supervisors may be in the tens of thousands, and cumulatively the number will be in the hundreds of thousands for all the companies involved.

Under the FDA proposed rule, it seems clear that the independent distributors who sell directly to consumers would qualify as "retailers" and be exempt from the registration requirement, but the status of the supervisors who sell to other independent distributors is not as clear. The preamble to the proposed rule states:

> The proposed rule would also require facilities that sell both directly to consumers and to distributors and wholesalers to register. Examples of these facilities are warehouse clubs. Because such facilities do not sell food directly to consumers only, they do not meet the definition of a ``retail facility." 68 Fed. Reg. 5383.

Direct sales distributors, however, are individuals and are not "facilities." CRN urges that all of these individuals be defined as "retailers" for purposes of the registration provision of the Bioterrorism Act and thus be exempt from registration. The parent corporation's manufacturing and distribution facilities will of course be registered, and there are provisions within each company for rapid communication between the corporation and its independent distributors (in both directions), should any problem arise involving the company's products.

Failure to clarify this point could result in flooding the registration system with hundreds of thousands of submissions that were not contemplated by the Act and that would not meaningfully assist FDA in its implementation.

Definition of "Foods" Should Not Include All Packaging Materials

By encompassing food packaging as well as foods *per* se, the proposed requirements appear to be more burdensome than necessary to accomplish the goal of the Bioterrorism Act to enhance FDA's ability to respond quickly to a threatened or actual attack on the U.S. food supply.

FDA's analysis of impacts makes it clear that the registration requirement will be interpreted as applying to facilities that manufacture, process, pack or store materials that

may be used for food packaging that contacts food. It was hoped that FDA would use its enforcement discretion and exempt packaging material manufacturers from the registration requirement. Instead, FDA appears to have used its discretion in the opposite direction, applying an expansive definition of food, and sweeping materials that are not even considered food additives within the scope of the registration requirement.

Further complicating matters is the fact that the **"food"** definition in the proposed rule requiring prior notice of food imports appears to apply to the same range of manufacturers of food packaging and food contact materials, even though the legislation contains language that might limit this application.

We urge FDA not to apply the registration or prior notice requirements to food packaging materials, **or at least to clearly limit the applicability to food contact materials**.

Other General Concerns Shared with the Conventional Food Industry

- Who submits the registration for each facility? CRN encourages FDA to be flexible in permitting companies to determine where within the corporation the responsibility lies for registering all facilities. In most cases, corporate headquarters may wish to carry the burden of registration for all its facilities, in order to maintain adequate control and to ensure that all requirements are met in a timely manner and updated as needed. The centralization of responsibility for registration within a company is not incompatible with FDA's likely intent to assign unique identification numbers for each facility.

- What is a facility? CRN also encourages FDA to permit some flexibility in defining a "facility." If a corporation has multiple buildings with different purposes at a single site, does that represent a single facility? If a corporation owns adjacent buildings with different addresses but treats them as a single operation, can those be defined as a single facility? These are judgments perhaps best made by the corporation, provided the registration meets the need to adequately identify each location at which food is manufactured, processed, packed, or held.

- Need to permit prompt registration of an unregistered foreign facility, when the failure to register is discovered at the point of import. CRN wishes to emphasize the importance of permitting an unregistered foreign facility to be registered promptly, ideally by electronic means, if a failure to register is noted late in the import process -- at the time prior notice of import is to be submitted, for example.

- Should food categories be required as a part of registration? The Act indicates that FDA may consider whether the registration should include identification of the product category held or handled at each facility, and mentions 21 CFR 170.3 as the appropriate reference in defining food categories. CRN wishes to point out that 170.3 does not include a product category for dietary supplements generally,

although it does include a category for "nutrient supplements." If FDA decides that the food category needs to be indicated, consideration must be given to whether 170.3 is currently adequate to meet the intended use.

Thank you for the opportunity to submit comments on issues relating to the implementation of the requirements of the Bioterrorism Act of 2002. CRN and its members look forward to working with FDA to facilitate timely implementation and will avail themselves of every opportunity for interaction and comment as this process moves forward, in order to provide the agency with adequate information needed to address the many concerns that will arise. CRN will be pleased to respond to any specific questions FDA may have regarding the dietary supplement industry, to the best of our ability.

Sincerely,

Annette Dickinson

Annette Dickinson
President